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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/813,990 | 03/22/2001 | Minako Hijikata | 205057US0SRD | 2667 |

22850 7590 07/11/2002

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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT PAPER NUMBER

1634

DATE MAILED: 07/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/813,990

Applicant(s)

HIJIKATA ET AL.

Examiner

Arun Chakrabarti

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 11, 12 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 11, 12 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9, 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

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DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of in Paper No. 14 is acknowledged. The traversal is on the ground(s) that there is no burden in examining the claims of Groups I with Groups II-IV. This is not found persuasive because as the restriction makes clear, additional search of Groups II-IV would require review not only of the 968 patents in class 536, subclass 22.1 for Group I but also 228 patents in class 435, subclass 94 for Group II, the 2364 patents in class 424, subclass 88 for Group III and the 268 patents in class 800, subclass 295 for Group IV. Review of these additional searches is prima facie evidence of burden which is not rebutted.

The traversal is also on the ground(s) that the office action merely states a conclusion on the relationship or unrelatedness between the groups while it fails to show any support behind the conclusion. This argument is not persuasive. As made clear in the restriction requirement that a polynucleotide sequence itself of Group I and method of sequencing a polynucleotide of Group II have different modes of operation, different functions or different effects which are distinct and apparent to an ordinary practitioner, thus providing strong support for the conclusion of restriction requirement. Same logic is applicable to the restriction requirement for other groups as clear reasoning and support has been provided for each relationship between the group(s).

The requirement is still deemed proper and is therefore made FINAL.

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Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-5, 11, 12, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4 and 11 are vague and indefinite over the recitation of the phrase, “validity” and “valid” respectively. It is not clear whether any effect of interferon therapy is meant or some specific or particular positive efficacy of therapy leading to recovery from a disease is meant. The metes and bounds of the claim are vague and indefinite.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-5, 11, 12, and 15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-5, 11, 12, and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods using the interferon alpha and beta for HCV-

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hepatitis treatment does not reasonably provide enablement for any interferon therapy for any disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The Court in *re Wands*, 8 USPQ2d 1400 (CA FC 1988) stated with regard to enablement that

“Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.”

Here, the claim is broadly drawn to detecting validity of any interferon therapy for any individual. However, the specification does not provide guidance commensurate in scope with this claim, teaching only two interferon alpha and beta resulting in induced hybridization reaction. The specification provides minimal guidance regarding methods for the identification of alternate interferon therapy other than interferon alpha and beta. There is one working example of HCV-hepatitis treatment. It is highly unpredictable whether or what other treatments would function in the context of other diseases or an oncogene database as Masson et al (*Clinical Pharmacokinetics*, (1997 April), Vol. 32(4), pages 324-343) teaches, “Therefore, the likelihood

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of response or toxicity is unpredictable a priori". It is therefore highly unpredictable whether other treatment strategies can be identified which meets this specific criteria regarding the treatment of malignant tumor. Further, as indicated by Masson et al. identification of additional treatment regiment will be by the trial and error method. This trial and error requirement is borne out because effects of chemotherapy on malignant tumor cannot be readily deduced, even where the metabolic pathways are known. Further, each malignancy has unpredictable effects on metabolic function, and no general method for a priori selection of treatment is presented. It would require a large amount of experimentation, potentially including the synthesis of hundreds of interferons, in order to identify additional metabolic pathways with the claimed functionality. Given the Wand's factors opposing the full scope of enablement including the limited teaching in the specification, the presence of only one working example, the teaching of unpredictability in the prior art, the unpredictability of the art, the breadth of the claim, and the large amount of experimentation needed, with only the skill level in the art being neutral towards enablement, it is concluded that undue experimentation is necessary to make and use the invention as broadly claimed.


Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti , Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

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supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,
Patent Examiner,
June 17, 2002


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600



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LIST OF RELATED CASES

AC
↓
AC

| <u>Docket Number</u> | <u>Serial or Patent No.</u> | <u>Filing or Issue Date</u> | <u>Status or Patentee</u> |
|----------------------|---------------------------------|---------------------------------|-------------------------------|
| 0039-3751-0S FWC CIP | 5,776,672 | 07/07/98 | HASHIMOTO et al. |
| 205057US0 SRD* | 09/813,990 | 03/22/01 | PENDING |
| 220633US2 SRD PCT | 10/070,415 | 03/15/02 | PENDING |

*Present application; listed for information.

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